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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,466	12/26/2000	Deguang Zhu		3400

27676 7590 07/21/2003
DEGUANG ZHU
718 WEST 171ST STREET, APT. 33
NEW YORK, NY 10032

EXAMINER

LAMM, MARINA

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 07/21/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/748,466

Applicant(s)

ZHU ET AL.

Examiner

Marina Lamm

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,6 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5,6 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the amendment filed 5/8/03. Claims pending are 5, 6 and 9-17. Claims 5, 6 and 9 have been amended. Claims 10-17 are new.

Claim Objections

1. Claims 15 and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 15 and 17 recite the limitation "wherein the composition is a solution or emulsion". Claims 15 and 17 either directly or indirectly depend from Claim 14 which recites the same limitation. Therefore, Claims 15 and 17 do not further limit the subject matter of a previous claim.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 as amended recites the limitation "said composition further consists essentially of cosmetically or pharmaceutically acceptable ingredients." This recitation is confusing because further inclusion of any cosmetically or pharmaceutically acceptable ingredients renders with the limitation "consisting essentially of" meaningless. It is unclear what

Art Unit: 1616

ingredients are excluded by the language “consists essentially of” if the compositions may contain any cosmetically or pharmaceutically acceptable ingredient. Therefore, the claim language presents uncertainty as to the scope of the claimed invention. For the purpose of examination the limitation “further consists essentially of” is being interpreted as “comprising”.

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The rejection of Claims 5, 6 and 9 under 35 U.S.C. 102(b) as being anticipated by Weiner is maintained for the reasons of the record.

6. The rejection of Claim 6 under 35 U.S.C. 102(e) as being anticipated by Danielov is maintained for the reasons of the record.

7. Claims 5, 6 and 9-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hinson (US 5,145,679).

Hinson teaches a method for treating skin conditions comprising topically applying to the surface of the skin a topical emollient which is a solution consisting essentially of glucose and insulin present as a concentration of 0.06-2 units/ml. See Abstract; col. 1, lines 13-17; col. 2, lines 34-36. The compositions of Hinson can be applied to the skin or scalp. See Examples. With respect to the limitations recited in the preambles of Claims 5 and 9, it is noted that newly discovered results of known processes (i.e. topically applying a compositions consisting essentially of insulin) are not patentable because such results are inherent. Since the method

step (i.e., topically applying a compositions consisting essentially of insulin) is the same, the result (i.e., increasing skin firmness, etc.) will inherently be the same.

Thus, Hinson teaches each and every limitation of Claims 5, 6 and 9-17.

Response to Arguments

8. Applicant's arguments filed 5/8/03 have been fully considered but they are not persuasive.

9. With respect to the rejection over the Danielov reference, the Applicant argues that Example 8 of Danielov describes an eye solution and the reference does not disclose or suggest topically applying the solution to the skin or scalp. In response, it is noted that Example 8 is not the only example that describes insulin-containing compositions. Examples 1, 2 and 3 of Danielov teach insulin-containing compositions for normal, dry and very dry skin, respectively. See col. 31, 33 and 35. With respect to the argument that Danielov does not teach either the claimed amount of insulin or the compositions consisting essentially of insulin, it is noted that the reference was not applied to the claims which recite either the specific amount of insulin or exclude other active ingredients.

10. With respect to the rejection over the Weiner reference, the Applicant argues that Weiner does not disclose a topical composition containing insulin. In response, it is noted that Weiner explicitly teach using the lipid excipient for delivery of peptides such as insulin, for both drug and cosmetic uses (i.e. for topical application). See Abstract; col. 7, lines 9-16; Claims 1, 3, 5. The reference's disclosure is not limited to the examples and have to be considered as a whole. With respect to the argument that Weiner does not teach the claimed

Art Unit: 1616

amount of insulin, it is noted that the reference was not applied to the claims which recite the specific amount of insulin.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (703) 306-4541. The examiner can normally be reached on Monday to Friday from 9 to 5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

ml
7/18/03


MICHAEL G. HARTLEY
PRIMARY EXAMINER